REMARKS

Amendments to the Claims

Claims 1, 4, 6-11, and 13-23 are pending. Claims 1 and 4-21 have been rejected. Claims 1, 19 and 23 are herein amended. Claims 2-3, 5, and 12 have been cancelled.

Claim 1 has been amended to specify the amount of mannitol per part of methylcellulose. Support for this amendment is found in cancelled claim 5. Claim 6 has not been cancelled.

Claim 19 has been amended to recite "obtainable." Support for this amendment in original claim 19.

Claim 23 has been amended to delete "further."

No new matter has been added.

Claim Rejections

The following remarks were included with the Amendment filed August 28, 2008. They are reproduced here for the Examiner's convenience.

Indefiniteness

The Examiner rejects claims 12-14 and 17-18 for indefiniteness stating that "[t]he claims are drawn to granule-like or 'tablet-like' preparations. These terms are indefinite as they are unclear what form is being claimed." Claim 12 has been cancelled. Claims 13 and 14 have been amended to recite a "solid" preparation, rather than "tablet-like." Claims 17 and 18 have been amended to recite "the form of a granule, a fine granule, or a powder." Applicants submit that these amendments clarify the claims and overcome the Examiner's indefiniteness rejection. Applicants request that the rejection be withdrawn.

The Examiner rejects claims 12, 14, and 17-19 as indefinite. The Examiner states that "[t]he claims are drawn to a solid composition comprising a particle with excipients but also recite the composition to be a granule which is also a particle." As discussed above, these claims have been amended to clarify the preparation of the invention. The "medicament-containing particle" is defined in claim 1 as having three essential ingredients: a medicament with an unpleasant taste, methylcellulose, and mannitol. However, the "medicament-containing particle" is not a final preparation, but a material or an intermediate for a final preparation. In comparison, the "solid preparation" defined in claims 11, 13-17 and the "intrabuccally rapidly disintegrating preparation" defined in claim 18 are final preparations. And, the "composition" defined in claim 19 is a composition for preparing the intrabuccally rapidly disintegrating preparation, which also comprises the "medicament-containing particle" as a material of the composition. Thus, the inventions in claims 11-19 and 21 include "medicament-containing particle" as a material/intermediate. See, e.g., Specification page 21, lines 19-25. The following relation describes the various relationships: "solid preparation" $\geq$ "composition" > "medicament-containing particle". Thus, Applicants submit that the terms "granule" and "particle" are clear. Applicants request that the rejection be withdrawn.

The Examiner comments that claim 19 appears to be a product by process claim and states that "it is not entirely clear the form of the preparation as addressed above, and for the purposes of examination the composition recited is a form comprised of the particles (granules) such as a tablet." Applicants have changed the language of claim 19 to clarify the relationship between the "medicament-containing particle" in comparison to the final composition. That is, the arrangement of components in claim 19 is such that there is the "intermediate" medicament - containing particle a) obtained by mixing and granulating a composition comprising a medicament, methylcellulone and mammitol, which in turn is then an ingredient of a composition further including ingredients b) and c). Thus, Applicants submit that claim 19 clearly claims the composition of the invention. Applicants request that the rejection be withdrawn.

Obviousness

Siebert

The Examiner rejects claims 1, 4-7, and 11-20 under 35 U.S.C. §103 as unpatentable over Siebert et al.. Applicants respectfully traverse.

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness. Because Siebert does not disclose a medicament-containing particle having methycellulose and mannitol, Siebert does not render obvious the present invention. Siebert discloses orally disintegrable dosage forms for the delivery of sustained or extended release microcapsules and/or prompt release coated or non-coated drug particles (see Siebert column 1, lines 9-12). Siebert also discloses that the tablet must be easy and pleasurable to swallow (see Siebert column 3, lines 8-9). However, the compositions which mask the unpleasant taste are quite different between the two inventions.

The present invention must include the "medicament-containing particle" which is comprised of the medicament, methylcellulose, and mannitol. In contrast to the final dosage form of Siebert, the present inventors have found that the use of methylcellulose and mannitol in the intermediate particle can mask an unpleasant taste without any special technique such as coating and microcapsulation.

On the contrary, Siebert discloses an orally disintegrable tablet for delivery of microcapsules and/or drug particles (see Siebert column 1, "Field of the invention"), and the "microcapsules and/or coated or non-coated drug particles" correspond to the "medicament-containing particle" in the present invention. Applicants submit that there is little practical explanation about materials of the "microcapsules and/or drug particles" in the description of the citation, i.e., column 2, lines 41-54; column 3, lines 47-62; column 5, lines 15-32; column 10, lines 42-53, and Examples 1 and 2. However, methylcellulose and mannitol are not described as ingredients of the composition *within* the microcapsules of Siebert (especially see, Siebert column 5, lines 15-

32).[1] Siebert does mention that mannitol and microcrystalline cellulose are ingredients of a complete tablet. The Examiner states that the disintegration properties and profiles are intrinsic to the composition. However, the Examiner is comparing a full tablet to medicament-containing particle of the present invention. Thus, Applicants submit that Siebert does not disclose each an every limitation of the present invention.

Furthermore, in Examples 1 and 2, a coated powder formulation (see Siebert column 11, upper table) and a microencapsule (see Siebert column 12, upper table) are shown respectively, which would correspond to the "medicament-containing particle" in the present invention. Both of the intermediates shown in the Examples lack methylcellulose and mannitol.[2] Furthermore, both the intermediates are coated with a coating solution so that the unpleasant taste could be masked (see Siebert column 11, lines 29-38, and column 12, lines 16-27). Thus, the disclosure of the prior art would not make the present invention obvious to one of skill in the art due to the means by which the composition masks an unpleasant taste, especially considering the coating of the invention disclosed in Siebert. Therefore, the citation does not disclose the "medicament-containing particle" of the present invention at all, and does not disclose or suggest the present invention. Applicants request that the rejection be withdrawn.

***Siebert, Depui, and Yoshinari* (and *Shirai*)**

The Examiner rejects claims 8-10, 18, and 21 as unpatentable over Siebert et al. in view of Depui et al., (U.S. Pat. No. 6368625) and Yoshinari et al., (US. Pat. No. 6235947) (and Shirai U.S. Patent 6,413,541). Applicants respectfully traverse.

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[1] Applicants note that the "coating" material may be made from hydroxypropyl methylcellulose phthalate, but do not equate the coating to the particle material or methylcellulose to hydroxypropyl methylcellulose phthalate to methylcellulose. Specifically, hydroxypropyl methyl cellulose phthalate is an enteric coating, meant to *prevent* disintegration until the microcapsule reaches the small intestine.

[2] Applicants note that tablets in Examples 1 and 2 of Siebert include mannitol and other excipients (see Siebert columns 11 and 12, lower tables), but the mannitol and other excipients are outside of the above-mentioned intermediate corresponding to "medicament-containing particle". Applicants suggest that claim 19 exemplifies the contrast between the microcapsules of Siebert and the medicament-containing particles of the present invention.

The Examiner states that "Depui teaches the usefulness and incorporation of mosapride to the treatment of gastro oesophageal reflux disease (GORD)." However, Depui does not teach or suggest that the mosapride should be in the form of a medicament containing particle, thus, does not remedy the deficiencies of Siebert.

The Examiner states that Yoshinari teaches "that D-mannitol is of high value as an excipient for high moisture sensitivity." Like Siebert and Depui above, Yoshinari does not suggest that any mannitol should be added to a medicament containing particle.

Shirai is cited only for the element in claim 21 of packaging, and this reference does not remedy the deficiencies of the combined disclosures of Siebert, Depui, and Yoshinari.

Thus Applicants submit that the combination of Siebert, Depui, and Yoshinari does not teach every element of the claims. Applicants submit that the Examiner has not made a prima facie case of obviousness. Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell Reg. No. 36,623 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By _____

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